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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,106	01/27/2004	Danny Lewis	PRJ-006CNRCE2	2190

959 7590 02/06/2008  
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ONE POST OFFICE SQUARE  
BOSTON, MA 02109-2127

EXAMINER
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AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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02/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/766,106

Applicant(s)

LEWIS ET AL.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-16, 19, 20, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16, 19, 20, 23, and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Receipt is acknowledged of the request for continued examination filed  
10/30/2007.

The following rejection is maintained in this office action:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all  
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148  
USPQ 459 (1966), that are applied for establishing a background for determining  
obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-16, 19, 20, 23, and 24 are rejected under 35 U.S.C. 103(a) as being  
unpatentable over Kinstler et al.

Kinstler et al. N-terminally chemically modified CSF and IFN by N-terminal  
monopegylation (see col. 10, lines 38-67). These modified peptides are then

incorporated into particulate preparations of polymeric compounds such as polylactic acid, polyglycolic acid or liposomes (see col. 11, lines 55-58). The teachings of Remington's Pharmaceutical Sciences, 18<sup>th</sup> Ed at col 11, line 61 includes microencapsulation at page 1663. The size of the particles formed by this process range from several tenths of a  $\mu\text{m}$  to 5,000  $\mu\text{m}$ . Alpha-interferon is specifically recited at col. 11, line 1. Those of ordinary skill would have found it well known to conjugate interferons or CSF with polyethylene glycol, and further to microencapsulate said conjugated bioactives in a biodegradable polymer such as polylactic or polyglycolic acids, and further to expect similar therapeutic results from the use thereof given the teachings of Kinstler et al. The instant invention would have been obvious to one of ordinary skill at the time of invention given the teachings of Kinstler et al.

#### ***Response to Arguments***

Applicant's arguments filed 10/30/2007 have been fully considered but they are not persuasive.

Applicant argues that the Kinstler reference does not inherently form a monophasic. As support, the oil in water emulsions of the instant application are cited. However, applicant also correctly points to the teaching of Kinstler which discloses a "homogeneous property" to the composition. Oil in water emulsions, and suspensions are recognized as non-homogeneous. The ordinary practitioner would recognize that solutions are homogeneous, and the composition of Kinstler is clearly a solution.

Applicant further argues that the reference does not teach a polymer derivatized protein conjugate which has hydrophilic and hydrophobic regions. However, in reviewing the reference for its broadest teachings, Kinstler includes combination of the interferon with PEG, and then addition of either polylactic and/or polyglycolic acid. This inherently forms both hydrophilic (PEG) and hydrophobic regions (polylactic or polyglycolic acid). Applicant's argument is therefore not persuasive.

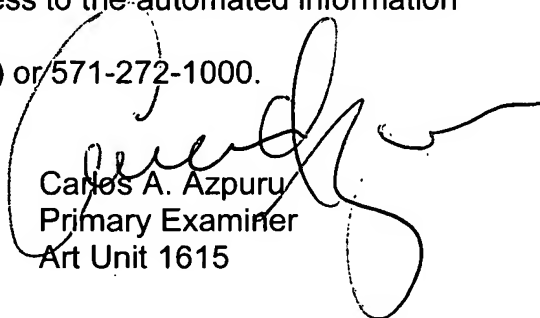
Regarding the claimed particle size, applicant argues that the reference does not teach a predominant size of 20 to 100 um. However, the reference must again be viewed for its broadest teaching. As such, the claimed particle size is well within the parameters of the teachings of the reference. Selection of any size (or size range) within that broad range is viewed as an optimization of the reference's teaching.

Therefore, applicant's arguments are not persuasive and the rejection under 35 USC 103(a) over Kinstler is maintained in this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615